

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

40-04

7/29/04

ADDITIONAL BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) SURVEILLANCE SAMPLING QUESTIONS AND ANSWERS

The Food Safety and Inspection Service (FSIS) is issuing this notice to provide answers to questions FSIS personnel have asked regarding FSIS' BSE surveillance sampling program.

I. Electronic Animal Disposition Reporting System (eADRS) and Performance- Based Inspection System (PBIS)

A. Question: What does an FSIS Public Health Veterinarian (PHV) document in eADRS when *non-ambulatory disabled* cattle are euthanized at the election of the establishment? Examples would be when the plants humanely euthanize an animal prior to the arrival of a PHV, or when an animal becomes non-ambulatory after antemortem inspection has been conducted?

Answer: In such cases, the antemortem disposition would be "dead," and the PHV records this in eADRS under "deads." The category "non-ambulatory (plant condemned)" is no longer available for cattle in eADRS. Also, in such cases, the PHV may write "Dead (Plant rejected and euthanized)" in the "Diagnosis/Condition" column of FSIS Form 6000-13, Certificate of Antemortem or Postmortem Disposition of Tagged Animals.

B. Question: Does the PBIS system schedule the brain sample collection for BSE testing?

Answer: No. FSIS personnel collect samples in accordance with FSIS Notices 28-04 and 29-04.

DISTRIBUTION: Inspection Offices;
T/A Inspectors; Plant Mgt; TRA;
ABB; TSC; Import Offices

NOTICE EXPIRES: 8/01/05

OPI: OPPED

II. Alternative Sampling -- Animal and Plant Health Inspection Service (APHIS) Central Sample Collection Point

A. Question: What are the animal identification collection and documentation procedures for cattle sampled under an accepted “alternative program” (APHIS central sample collection point)?

Answer: Normal documentation procedures apply, including recording the condemned tag number and all animal identification (e.g., eartag, backtag) on FSIS Form 6150-1 (Identification Tag-Antemortem). However, in this case the animal identification tags or devices will remain on the animal or handled in accordance with an accepted alternative method. Condemned tags should be removed prior to transport and after the carcass has been denatured in accordance with 9 CFR 314.

B. Question: What responsibility does the FSIS PHV have to provide information to plant management for cattle sampled under an acceptable alternative program (APHIS central sample collection point)?

Answer: The FSIS PHV's responsibility is to supply plant management with copies of FSIS Form 6000-13, Certificate of Antemortem or Postmortem Disposition of Tagged Animals, that includes the condemned tag number. The establishment may also request to make copies of FSIS Form 6150-1. The establishment may use this information to fulfill the expectation of FSIS Notice 29-04 concerning alternative programs to ensure that the animal identification information and condemned tag number (although not physically attached) remain associated with the animal.

III. State, Talmadge-Aiken (T/A), and Custom-Exempt Establishments

A. Question: How is the sampling handled at T/A plants?

Answer: FSIS will perform sampling in TA plants. If sample collection is needed, the state coordinator should contact the District Office (DO).

B. Question: How is the sampling handled at State plants?

Answer: State plants should contact the State Area Veterinarian-in-Charge (AVIC) for sample collection. Any alternative programs for sampling off-premises must be consistent with FSIS Notice 29-04.

C. Question: At federally-inspected establishments, who is responsible for collecting brain samples from animals designated “for custom slaughter” and that are non-ambulatory disabled cattle or cattle that exhibit Central Nervous System (CNS) signs?

Answer: When an establishment's schedule of operations indicates that the establishment is operating under custom exempt, those animals are exempt from the inspection requirements of the Federal Meat Inspection Act (FMIA). Because custom exempt cattle that are non-ambulatory disabled or that exhibit CNS signs are unfit for food, inspection program personnel who observe cattle with these signs being

slaughtered for food are to detain the carcass and head in accordance with FSIS Directive 8410.1, rev 2. Inspection program personnel also are to contact the DO.

The DO will assign a PHV to collect and submit a brain sample for BSE testing. In addition, the PHV is to notify the OPEER Regional Manager through supervisory channels.

IV. Sample Collection

A. Question: How will personnel be dispatched to collect samples at federally-inspected establishments?

Answer. District Managers will handle this within their districts according to staffing needs.

B. Question: Does the PHV have to be present when the head is removed?

Answer: While it is preferable that the PHV be present at the time of head removal, some situations (e.g., non-ambulatory disabled cattle that have been euthanized by the plant) may require removal of the head prior to the arrival of a PHV. The process for removal, storage, and control of the head and carcass denaturing should be decided during the awareness meeting with plant personnel if it is anticipated that removal of the head in the absence of the PHV may be necessary. The establishment's process should also ensure that sufficient controls are in place to maintain the identity of the animal.

C. Question: Are instruments used only to harvest the sample required to be sanitized?

Answer: No, but thorough washing is recommended. It would be preferable that dedicated or disposable instruments be used to harvest samples for BSE testing.

D. Question: How is the determination made that the animal is 400 lb. or less?

Answer: The PHV must rely on his or her judgment, expertise, or any other resources (e.g., records or actual weighing of animal) to determine the approximate weight of the animal.

E. Question: Are dead calves (i.e., less than 400 lbs.) sampled?

Answer: No, because such animals are not part of the high-risk population identified by APHIS.

F. Question: Who is responsible for sampling dead cattle off-loaded onto plant-owned property that is adjoining to, but not considered part of, the "official premises"?

Answer: Such cattle would be subject to sampling by APHIS.

G. Question: What is considered to be “presented for antemortem inspection”?

Answer: Live cattle that are off-loaded from transportation vehicles are considered to be presented for inspection and, therefore, are to be tested under FSIS Notice 28-04, where applicable. Dead cattle that are off-loaded to facilitate the off-loading of live animals, but that will be promptly re-loaded onto the transport vehicle, are not subject to sampling by FSIS.

H. Question: Does the head always have to be removed when harvesting samples?

Answer: PHVs have been trained to remove the head in order to collect the sample. If a plant is exposing the brain stem for sample collection by the PHV, the PHV will determine whether a sample can be adequately collected. Although PHVs can work with the plant to determine other efficient and suitable methods, decisions on the adequacy of sample collection procedures are the responsibility of the PHV.

I. Question: How is BSE sampling handled at small plants where there is no PHV?

Answer: The PHV responsible for final disposition in that plant should be contacted. If the animal is condemned, the DO will follow its procedures for arranging for sample collection by a trained PHV.

J. Question: What procedures should be followed for head removal after an animal is U. S. condemned and euthanized?

Answer: It is recommended that the establishment remove the head for FSIS sampling as soon as possible. FSIS sampling (including head removal if not performed by the establishment) may take precedence over other antemortem or postmortem procedures.

K. Question: Can the plant use the suspect pen for sampling?

Answer: The plant can use the suspect pen, provided humane handling and inspection of other animals in the suspect pen is not affected. Regardless of where the sampling is performed, sanitary conditions must be maintained.

V. Carcass Disposal

A. Question: If the plant takes the carcasses to a landfill, whose jurisdiction does this fall under?

Answer: This will be the responsibility of state or local authorities. FSIS personnel need only verify through plant records that the carcasses did in fact go to the landfill.

B. Question: Can the establishment dispose of the carcass prior to receiving lab results?

Answer: Yes. Because the animal was condemned at antemortem inspection, there is no requirement for establishments to hold carcasses. FSIS is recommending that establishments make arrangements to confirm negative results prior to these carcasses being rendered. This would not be an issue for carcasses going to incineration, alkaline digestion, or a lined landfill. Also, local sanitary codes are applicable.

C. Question: Can establishments remove carcasses from the premises outside of the official hours of operation without being sampled?

Answer: Yes. There are no regulations which would prohibit this from occurring. However, establishments remain subject to the FMIA denaturing requirements for such carcasses (21 USC 641). FSIS is committed to sample all available carcasses during established hours of operation.

VI. Sample Integrity

A. Question: Is the PHV responsible for determining whether the sample is of acceptable quality (i.e., whether autolysis has not occurred) before submitting a sample to the laboratory?

Answer: The PHV is responsible for the timely collection of and proper shipping of collected samples to the laboratory. PHVs are not responsible for making the determinations about the quality of the collected samples for their diagnostic suitability. If the collected samples have to be held prior to shipping they are to be held in cold storage, not frozen.

B. Question: When extracting the brain stem, what distance above and below the "V" (obex) do you allow?

Answer: The cut should be made approximately ½ to 1 inch above and below the obex.

C. Question: If the obex is unavailable, is there any other tissue which can be submitted for testing?

Answer: No, the obex is the only location we are currently testing.

D. Question: Can the obex be moistened to facilitate its entry into the tube?

Answer: No.

E. Question: Should the sample be washed/rinsed to remove blood clots?

Answer: No. APHIS prefers that blood clots are removed by hand and the sample be blotted with a paper towel.

F. Question: Is it necessary to attach an FSIS security seal to sample?

Answer: No.

G. Question: Because samples cannot be stored or passed through areas in which there is edible product, how can establishments store these samples?

Answer: Plants may have a dedicated refrigerator for samples in the inspection office or elsewhere that can be reached without passing through edible areas. Different options should be discussed during the awareness meeting, and could include, for example, use of a portable cooler.

H. Question: What if the brain stem is mutilated due to the method used to euthanize the animal?

Answer: Submit the sample and write on the sample form that the sample was mutilated prior to collection.

VII. Laboratory Results

A. Question: How long does it take to receive results after the brain sample is submitted?

Answer: The laboratories generally report the results 36 to 48 hours after the sample is shipped.

B. Question: Who will receive the results?

Answer: A report of the test results will be sent to the submitter, the AVIC, and the establishment, if requested.

C. Question: Will the results of the BSE test be posted on Laboratory Electronic Application for Results Notification (LEARN)?

Answer: No, not at this time.

D. Question: Other than reporting positive results, what will the laboratory report state?

Answer: The laboratory report may state one of the following: **“Not Detectable”** which indicates that the sample was tested and the results were negative; **“Location”** which could mean that the sample appeared to be a brain stem, but could not be identified as the obex; or **“Not Tested”** or **“Not Testable”** which means that the sample could not be recognized as a brain stem or that it was autolyzed.

E. Question: How may a carcass be disposed of when a result of “Not Tested” or “Not Testable” is received?

Answer: If a test was not conducted, plants may dispose of such carcasses by any available means such as inedible rendering, incineration, alkaline digestion, or movement to lined landfills in accordance with state or local codes.

VIII. Documentation

A. Question: What if the name and address of the owner are not available at the time of sampling?

Answer: The sample should be collected and submitted as soon as possible. The missing information can be sent at a later date when it becomes available (this information should be sent regardless of whether the sample results are positive or negative). This information should be made available in accordance with the recordkeeping requirements in 9 CFR part 320.

B. Question: Is it sufficient to identify a broker or auction house as the owner of the animal?

Answer: Every attempt should be made to attain the actual producer’s name and address. However, if that cannot be obtained, identify a broker or auction house as the owner.

C. Question: Is filling out FSIS Form 6000-13 mandatory?

Answer: No. For antemortem condemned cattle, complete FSIS Form 6000-13 when requested by plant management. Consistent with their training for collection of BSE samples, PHV’s are to maintain a file on each sampled animal. PHVs can use either a Form 6000-13, 6200-14, or 6150-1 to capture the condemnation Z-tag number of sampled animals. For plants with alternative procedures for off-site sampling, FSIS Form 6000-13 may be requested to facilitate correlations with the condemnation Z-tag number.

D. Question: Should animal identification (e.g., eartags, backtags) be collected and saved until sample results are received?

Answer: Yes, they should be saved in a plastic bag in association with the dedicated file. Do not send these items with the sample.

E. Question: How should “deads” be recorded in the “Clinical Signs” section of the APHIS form, Veterinary Services (VS) Form 10-4 - Supplemental Form?

Answer: Check the box marked “other” at the bottom-right portion of this section, and write in “dead” below it.

F. Question: Is the barcode placed on the copy of the condemnation form, or on the original?

Answer: On the copy (second sheet) that is maintained by FSIS. The original goes to the establishment.

G. Question: Is it mandatory to complete FSIS Form 5000-11, BSE Sampling Tracking Sheet?

Answer: Use of FSIS Form 5000-11 by PHVs who collect BSE samples is mandatory. The only acceptable version of this form is in Form Flow. The form is only to be used when FSIS personnel actually collect the sample. PHVs are to provide complete and accurate entries of all items on FSIS Form 5000-11. PHVs are to indicate the appropriate age to the best of their abilities. The forms should be either mailed or faxed to the Financial Processing Center (FPC). PHVs are not to submit duplicates because this would require FPC to verify the forms twice. Whether by mail or fax, PHVs can submit Form 5000-11 to the FPC on weekly basis. The form does not have to be submitted daily. Also, the PHV is not to submit other forms (e.g., FSIS Form 6000-13 or VS Form 10-4) to FPC. PHVs that collect a sample during a reimbursable overtime period are to note this in the provided check box, not in the remarks section. Established forms or timesheets should continue to be completed for regular and overtime hours.

H. Question: Should a copy of FSIS Form 5000-11 be sent with the sample?

Answer: No.

I. Question: Can unused sets of barcodes be utilized at a later date?

Answer: Yes, unused entire sets of barcodes can be utilized for future samples. Since each set represents a unique number, use one set of barcodes for each sample. Do not use incomplete sets. Destroy incomplete sets.

IX. Sample Shipping

A. Question: If a sample is collected on a Saturday, Sunday, or holiday, should the sample be held?

Answer: Yes, the sample should be held until the next available Federal Express pick-up.

B. Question: When a sample is sent, will the laboratory automatically return the shipping container?

Answer: National Veterinary Services Laboratory (NVSL) will automatically return the shipping container. However, the other labs do not provide automatic returns.

Therefore, sufficient sampling supplies should be maintained by ordering through NVSL (Ames, IA).

C. Question: Should unused tubes be saved?

Answer: Yes. They can be used for subsequent sampling.

D. Question: What is the turnaround time on shipping containers sent to NVSL?

Answer: Approximately five days. In an emergency, APHIS can ship overnight.

E. Question: Are the fax forms available for requesting overnight delivery of shipping containers?

Answer: Yes. This form (BSE Kit and Instrument Order Form) is available on Outlook "All Public Folders/OFO/Technical Service Center/BSE Training Info."

F. Question: Can the same shipping container for samples from 2 different establishments be used?

Answer: Yes, as long as the paperwork and equipment (e.g., tubes) are separate and properly identified.

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